UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

ANNETTE CARTER, individually and on behalf of others similarly situated,	)	
Plaintiff,	)	
v.	)	Case No. 4:13CV00977 AGF
ALCON LABORATORIES, INC., and ALCON RESEARCH, LTD.,	)	
Defendants.	)	

MEMORANDUM AND ORDER

This putative class action is before the Court on Defendants' motion (Doc. No. 11) to dismiss Plaintiff's first amended complaint pursuant to Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim upon which relief can be granted, and alternatively, on federal preemption grounds. For the reasons set forth below, the Court concludes that although Plaintiff's claims are not preempted, she has failed to state a claim under Missouri law.

BACKGROUND

Moxeza, Vigamox, and Nevanac are prescription eye drops manufactured and sold by Defendants, residents of Delaware and Texas, for the treatment of short-term conditions such as bacterial conjunctivitis and post-surgical inflammation. Vigamox is sold for use by consumers in 4 milliliter ("mL") bottles that contain 3 mL of medication. The recommended dosage of Vigamox is one drop of 38 microliters ("μL") in the affected eye three times a day for seven days, which in total is approximately 0.8 mL of medication.

Thus, a consumer who used the minimum amount of 0.8 mL of Vigamox would be left with approximately 2.2 mL of unneeded medication at the end of the course of treatment.

Moxeza is sold in 4 mL bottles that contain 3.0 mL of medication. The recommended dosage is 50 μL in the affected eye two times daily for seven days. Thus, a patient requires 0.7 mL of medication to complete a course of treatment, meaning that 2.3 mL may be unused. Nevanac is sold in 4 mL bottles that contain 3.0 mL of medication. The recommended dosage is 50 μL in the affected eye three times daily, for approximately two weeks. This means that a patient requires 2.4 mL of medication to complete a course of treatment, so 0.6 mL may be unused.

In the Complaint, Plaintiff alleges that the FDA approved sample bottles of the subject medications that contain 1 mL of medication, and that Defendants "know that the amounts contained in the 'physician sample' bottles are sufficient for consumers to complete the typical prescription." (Doc. No. 1, ¶¶ 20, 22.) [1]

Plaintiff Annette Carter, a Missouri resident, alleges that she purchased and used Vigamox for a single course of treatment and had to discard "large portions" because Defendants "overfilled" the bottles. She brings this class action individually and on behalf of the class of Missouri consumers who purchased any of the three subject medications for a course of treatment. Plaintiff's complaint is based on Defendants' alleged "illegal practice of filling and selling dispensers with much more medication than could be used" so that consumers are forced to purchase more medication than they need.

[1] The Court notes that, based on Plaintiff's own allegation in ¶ 22, the sample size of Nevanac was not enough to complete a typical course of treatment as described in the complaint.

Plaintiff alleges that Defendants "set the price of the subject medications based upon the amount of medication in each container" and that "[i]f Defendants made the [smaller] 'sample' size available for consumer purchase, the prescriptions would be less expensive and consumers would spend less money on the medications." According to Plaintiff, Defendants "increase their profits by filling and selling topical ophthalmic prescription medications for single courses of treatment . . . only in a form and in quantities that they know greatly exceed the amount needed by the consumer and will inherently lead to wastage of expensive medication through no fault of the consumers." These alleged profits, Plaintiff contends, constitute an economic harm to Plaintiff because there is "no valid reason" for Defendants to overfill the subject medications' bottles and therefore compel consumers to "purchas[e] unwanted quantities of the medication."

Count I of Plaintiff's first amended complaint alleges violations of the Missouri Merchandising Practices Act ("MMPA"), which makes unlawful "[t]he act, use or employment . . . of any deception, fraud, false pretense, false promise, misrepresentation, [or] unfair practice . . . in connection with the sale or advertisement of any merchandise . . . ." Mo. Rev. Stat. § 407.020.1. Count II claims that Defendants were unjustly enriched by the receipt of excessive and unfair payments because of their deceptive and unfair activities, and Count III, for money had and received, similarly asserts that Defendants have received money from unfair practices. Plaintiff requests appointment as class representative and Plaintiff's counsel as counsel for the class, and seeks actual damages, punitive damages, declaratory and injunctive relief, and reasonable attorney's fees and costs.

ARGUMENTS OF THE PARTIES

1. Failure to State a Claim

Defendants argue that Plaintiff's claims do not satisfy the plausibility standard of *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007), because they fail to allege a cognizable unfair practice under the MMPA. Defendants further contend that as Plaintiff does not allege that she purchased Moxeza or Nevanac, she cannot state a claim, either on her own behalf or on behalf of a class, under the MMPA based on products she did not purchase. With respect to Vigamox, Defendants argue that Plaintiff has not pled that she suffered an ascertainable loss, which is an essential element for a claim under the MMPA, because she does not allege that she failed to receive the benefit of her bargain, that is, a safe and effective product that worked as intended. Defendants maintain that in any event, Plaintiff fails to allege facts establishing a causal connection between Defendants' challenged conduct and any purported loss, as the prescribing physician's exercise of medical judgment in prescribing the trade bottle rather than giving Plaintiff a sample to use, breaks that causal link. Defendants argue that Plaintiff's equitable claims for unjust enrichment and money had and received fail because they are based on the same nonactionable conduct as the MMPA claim.

In response, Plaintiff contends that she sufficiently pled that Defendants' conduct of selling quantities of medication that could not be used is an unfair practice. She argues that whether she may maintain an action on behalf of others based on the two medications she did not purchase should be decided at the class certification stage, as courts have held that a plaintiff has standing to assert such claims if the products and challenged practices

are substantially similar. Plaintiff asserts that she adequately pled an ascertainable loss by alleging that she paid for portions of medication that were unusable, and the physician's intervention did not break the causal chain between the purchase and the injury.

With respect to her common law claims, Plaintiff argues that Defendants' profits and benefits were to Plaintiff's detriment and "[t]o allow Defendants to retain what consumers paid for amounts of medication that they could not use would be unjust." Finally, Plaintiff argues that she states a claim for money had and received based on Defendants' deceptive and unfair practice, money which, in equity and good conscience, ought to be returned to consumers.

Defendants reply that, even under a broad consumer protection statute, the purchase of safe and effective medication at fully disclosed volumes and dosages cannot be construed as an unfair practice, absent allegations of fraud or duress, which is not alleged here. They contend that the voluntary purchase of the larger bottle instead of getting a free smaller sample bottle cannot be construed as an unfair practice. According to Defendants, Plaintiff and her doctor chose the larger bottle over the smaller free bottle, and therefore the excess medication was not unwanted goods.

2. Federal Preemption

Defendants argue that Plaintiff's claims are preempted by federal law because Defendants are unable to change the subject medications' fill volume and/or bottle size without prior FDA approval. In support of this argument, Defendants point to ***PLIVA, Inc. v. Mensing***, 131 S. Ct. 2567, 2581 (2011) (holding that inadequate warning claims against generic drug manufacturers were preempted by federal law because federal law does not

permit the generic manufacturers to change their product labels without prior FDA approval), and *Mutual Pharmaceutical Co. v. Bartlett*, 133 S. Ct. 2466 (2013) (holding that state-law claims that require major changes to, *inter alia*, the "quantitative formulation" or "the specifications provided in the approved application" for the drug are in conflict with, and therefor preempted by, federal law which forbids such changes without prior FDA approval). Defendants also point to federal law that prohibits the sale of samples.

In response, Plaintiff argues that Defendants have not met their burden of establishing the affirmative defense of federal preemption because the FDA has authorized the sample bottles with smaller fill volumes, which could be converted into trade products without the FDA's prior approval, but rather upon notice to the FDA. In support of her position, Plaintiff points to *Wyeth v. Levine*, 555 U.S. 555, 573 (2009) (holding that a brand-name drug manufacturer had to prove by clear evidence that the FDA would not have approved a labeling change that required notice to, but not prior approval of, the FDA, before a state law claim is preempted).

DISCUSSION

Failure to State a Claim

To survive Defendants' motion to dismiss, Plaintiff's claims must contain sufficient factual matter, accepted as true, to "'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Twombly*, 550 U.S. at 570). "[F]ormulaic recitation of the elements of a cause of action will not do;" this standard "calls for enough facts to raise a reasonable expectation that discovery will reveal evidence of [the claim]." *Twombly*, 550 U.S. at 555-556.

The reviewing court must accept the plaintiff's factual allegations as true and construe them in plaintiff's favor, but is not required to accept the legal conclusions the plaintiff draws from the facts alleged. *Iqbal*, 556 U.S. at 678; *Retro Television Network, Inc. v. Luken Commc'ns, LLC*, 696 F.3d 766, 768-69 (8th Cir. 2012). A court must '"draw on its judicial experience and common sense,'" and consider the plausibility of the plaintiff's claim as a whole, not the plausibility of each individual allegation. *Zoltek Corp. v. Structural Polymer Group*, 592 F.3d 893, 896 n. 4 (8th Cir. 2010) (quoting *Iqbal*, 556 U.S. at 679).

"When a federal court sits in diversity, it must apply the governing precedent from the state's highest court, and when there is no case directly on point, the federal court must predict how the state supreme court would rule if faced with the same question." *Jordan v. Safeco Ins. Co. of Ill.*, 741 F.3d 882, 887 (8th Cir. 2014).

To state a claim under the MMPA, Plaintiff must show that (1) she purchased the merchandise in question; (2) she purchased the merchandise for personal, family, or household use; (3) she suffered an ascertainable loss; and (4) the ascertainable loss was the result of an unfair practice. Mo. Rev. Stat. § 407.025.1; *Polk v. KV Pharm. Co.*, No. 4:09-CV-00588 SNLJ, 2011WL 6257466, at *4 (E.D. Mo. Dec. 15, 2011). Missouri courts consider that the state legislature enacted chapter 407 to "regulate the marketplace to the advantage of those traditionally thought to have unequal bargaining power as well as those who may fall victim to unfair business practices." *Huch v. Charter Commc'ns., Inc.*, 290 S.W.3d 721, 725 (Mo. 2009). "Ultimately, the MMPA requires courts to make case-by-case determinations of whether a defendant's conduct violates principles of fair

dealing." *Toben v. Bridgestone Retail Operations, LLC*, No. 4:11–CV–1834 CEJ, 2013 WL 5406463, at *2 (E.D. Mo. Sept. 25, 2013) (citing *Huch*, 290 S.W.3d at 724).

Although unfair practices are not defined in the MMPA, the Act empowers the state attorney general to promulgate rules necessary to administer and enforce it, and such rules have "independent power as law." *Huch*, 290 S.W.3d at 725. One of the rules promulgated by the attorney general is 15 CSR [Missouri Code of State Regulations] 60–8.020(1), which defines an unfair practice as one that "(A) Either — 1. Offends any public policy as it has been established by the Constitution, statutes or common law of this state . . . ; or 2. Is unethical, oppressive or unscrupulous; and (B) Presents a risk of, or causes, substantial injury to consumers." 15 CSR 60–8.020(1).

An ascertainable loss of money or property is an essential element of a cause of action brought under the MMPA. *Freeman Health Sys. v. Wass*, 124 S.W.3d 504, 508 (Mo. Ct. App. 2004). Under the benefit-of-the-bargain test, which awards a prevailing party the difference between the value of the product as represented and the actual value of the product as received, Plaintiff has not suffered an ascertainable loss. Plaintiff does not allege that the medication she purchased was anything other than represented or that it did not perform as intended.

The Court concludes that even without applying the benefit-of-the-bargain test for loss under the MMPA, Plaintiff has failed to state a claim. Plaintiff's theory of her loss is the difference between what Defendants charge for the medication bottle available to consumers and the price they would charge for a bottle with less medication. However, even if Defendants sold bottles with less medication, Plaintiff has not suggested there is

anything to preclude them from charging what they now charge for the bottles currently available for purchase. Plaintiff has cited no authority from any jurisdiction suggesting that a drug manufacturer's choice of volume fill is an unfair practice, and this Court concludes that the Missouri Supreme Court would find that absent fraud or duress or price gauging, none of which were alleged here, no such cause of action exists under the MMPA.

Similarly, Plaintiff's claims for unjust enrichment and money had and received also fail. *See Miller v. Horn*, 254 S.W.3d 920, 924 (Mo. Ct. App. 2008) (stating that an element of unjust enrichment is "that the enrichment was at the expense of the plaintiff"); *Springfield Land & Dev. Co. v. Bass*, 48 S.W.3d 620, 631 (Mo. Ct. App. 2001) (stating that an action for money seeks to reach monies which ought to be paid to the plaintiff); *see also Toben*, 2013 WL 5406463, at *3 (dismissing unjust enrichment and money had and received claims after finding that the plaintiff had failed to state a claim under the MMPA).

Federal Preemption

With respect to Defendants' second argument for dismissal, the Court agrees with Plaintiff that Defendants have not met their burden to establish federal preemption here. In *PLIVA* and *Bartlett* the Supreme Court held that state claims that would require relabeling (*PLIVA*) or redesign (*Bartlett*) of a drug that could not be done by the manufacturer without prior approval by the FDA are preempted. Under FDA regulations, once a drug is approved, the manufacturer is prohibited from making any "major changes" absent a supplement submission and approval. 21 C.F.R. § 314.70(b). "Major changes" are "any change in the drug substance, drug product, production process, quality controls, equipment, or facilities that has a substantial potential to have an adverse effect on the

identity, strength, quality, purity, or potency of the drug product as these factors may relate to the safety or effectiveness of the drug product." 21 C.F.R. § 314.70(b)(1).

Based on the record before the Court, Defendants have not established that prior approval by the FDA would be required to sell bottles of the three medications in question in the same size as their approved sample size. If only notice subsequent to the change is required, Defendants have not established that the FDA would not have approved such a change.

Defendants' preemption argument relies in part on restrictions on selling drug samples, but such restrictions are irrelevant. Plaintiff is not asking Defendants to sell samples, but rather sell trade bottles in the same size as the FDA has approved for the sample bottles.

CONCLUSION

Accordingly,

IT IS HEREBY ORDERED that Defendants' motion to dismiss Plaintiff's first amended complaint is **GRANTED**. (Doc. No. 11.)

A separate Judgment shall accompany this Memorandum and Order.

Audrey G. Fleissig

AUDREY G. FLEISSIG
UNITED STATES DISTRICT JUDGE

Dated this 13th day of March, 2014.